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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/077,574	09/24/1998	MICHAEL PANACCIO	DAVIE60001AP	6196

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/077,574	PANACCIO ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,12,32,33,37,39,40 and 114-116* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,12,32,33,37,39,40 and 114-116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 June 1998* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Request for Continued Examination

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 11/24/03 has been entered.

Applicants' Amendments

2) Acknowledgment is made of Applicants' amendment filed 07/06/04, 05/27/04, 03/08/04 and 11/24/03 in response to the final Office Action mailed 02/20/03. With one or more of these, Applicants have amended the specification.

Status of Claims

3) Claims 1, 2, 12, 32, 37, 39, 40, 114 and 115 have been amended via the amendment filed 11/24/03.

Claims 3-11, 13-31, 34-36, 38 and 41-113 have been canceled via the amendment filed 11/24/03.

New claim 116 has been added via the amendment filed 11/24/03.

Claims 12, 114 and 115 have been amended via the amendment filed 03/08/04.

Claims 1 and 114 have been amended via the amendment filed 5/27/04.

Claims 1, 2, 12, 32, 33, 37, 39, 40 and 114-116 are pending.

The previously withdrawn claim 33 is now rejoined with the examined claims.

Claims 1, 2, 12, 32, 33, 37, 39, 40 and 114-116, all encompassing SEQ ID NO: 2, are under examination.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Moot

6) The objection to claim 41 made in paragraph 35(b) of the Office Action mailed 05/30/02 is moot in light of Applicants' cancellation of the claim.

Rejection(s) Moot

7) The rejection of claim 41 made in paragraph 31 of the Office Action mailed 05/30/02 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claim.

8) The rejection of claims 6-10, 38, 41, 43, 94, 95, 108 and 109 made in paragraph 32 of the Office Action mailed 05/30/02 under 35 U.S.C. § 112, first paragraph, as being non-enabled, is moot in light of Applicants' cancellation of the claims.

9) The rejection of claims 41, 43 and 109 made in paragraph 33 of the Office Action mailed 05/30/02 under 35 U.S.C. § 112, first paragraph, as being non-enabled, is moot in light of Applicants' cancellation of the claims.

10) The rejection of claim 41 made in paragraphs 34(a) and 34(i) of the Office Action mailed 05/30/02 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

11) The rejection of claims 6-9, 38, 43 and 109 made in paragraph 34(j) of the Office Action mailed 05/30/02 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

12) The rejection of claim 94 made in paragraph 31(a) of the Office Action mailed 02/20/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

13) The rejection of claims 6-8, 94 and 95 made in paragraph 31(b) of the Office Action mailed 02/20/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

14) The rejection of claim 9 made in paragraphs 31(c) and 31(e) of the Office Action mailed 02/20/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

15) The rejection of claims 6-9 and 38 made in paragraph 31(g) of the Office Action mailed 02/20/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

16) The rejection of claims 1 and 2 made in paragraph 14 of the Office Action mailed 08/29/01 and maintained in paragraph 26 of the Office Action mailed 05/30/02 under 35 U.S.C. § 102(e) as being anticipated by Knittel *et al.* (US 5,714,375) as evidenced by Lemarchand *et al.* (*Vet. Pathol.* 34: 152-156, March 1997, abstract), is withdrawn in light of Applicants' amendments to the base claim.

17) The rejection of claims 1, 2, 12, 32, 37, 39, 40, 114 and 115 made in paragraph 32 of the Office Action mailed 05/30/02 under 35 U.S.C. § 112, first paragraph, as being non-enabled, is withdrawn in light of Applicants' amendments to the claims and/or the base claim(s).

18) The rejection of claims 1 and 32 made in paragraphs 34(a) and 34(i) of the Office Action mailed 05/30/02 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

19) The rejection of claims 2, 37, 39, 40, 114 and 115 made in paragraph 34(j) of the Office Action mailed 05/30/02 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

20) The rejection of claims 1 and 32 made in paragraph 31(b) of the Office Action mailed 02/20/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

21) The rejection of claim 115 made in paragraph 31(d) of the Office Action mailed 02/20/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

22) The rejection of claim 40 made in paragraph 31(f) of the Office Action mailed 02/20/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

23) The rejection of claims 2, 37, 39, 40, 114 and 115 made in paragraph 31(g) of the Office

Action mailed 02/20/03 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

24) The rejection of claims 1 and 2 made in paragraph 33 of the Office Action mailed 02/20/03 under 35 U.S.C. § 102(a) as being anticipated by McOrist *et al.* (*Int. J. Syst. Bacteriol.* 45: 820-825, October 1995) (McOrist *et al.*, 1995), is withdrawn in light of Applicants' amendment to the claims.

25) The rejection of claims made in paragraph 34 of the Office Action mailed 02/20/03 under 35 U.S.C. § 102(b) as being anticipated by McOrist *et al.* (*Infect. Immun.* 57: 957-962, 1989) (McOrist *et al.*, 1989), is withdrawn in light of Applicants' amendment to the claims.

Rejection(s) under 35 U.S.C. 112, First Paragraph (New Matter)

26) Claims 37, 39 and 40 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 37 was amended via the amendment filed 24 November 2003 to recite: 'composition further comprises a second peptide or protein from *L. intracellularis'*. Claim 39 was amended via the amendment filed 24 November 2003 to recite: 'claim 37, wherein the second peptide or protein is in recombinant form'. Claim 40 was also amended to recite: 'method according to Claim 37, wherein the second protein is selected from the group consisting of: a refolding protein, a second heatshock protein, a flagellar basal body rod protein, an S-adenosylmethionine, ...glucarate transporter'. However, there appears to be no descriptive support in the specification as filed for the claimed method which uses a composition comprising an isolated immunogenic heatshock protein of *L. intracellularis* having the amino acid sequence of SEQ ID NO: 2 and 'a second peptide or protein from *L. intracellularis'*, wherein 'the second peptide or protein is in recombinant form', and wherein 'the second protein' is selected from the group consisting of: a refolding protein, 'a second heatshock protein', a flagellar basal body rod protein, an S-adenosylmethionine, ...glucarate transporter'. A review of the specification indicates that a 'second heterologous ... protein' in relation to a 'recombinant molecule' or 'fusion molecule' is supported in the last part of page 5 of the specification. The paragraph bridging pages 5 and 6 of the instant specification is

limited to a 'recombinant vaccine' comprising one or more 'recombinant peptides, polypeptides or proteins' from *L. intracellularis*. The 'second' peptide, polypeptide or protein is specifically limited to 'a second heterologous peptide, polypeptide or protein .... useful as a carrier molecule or an adjuvant or an immune stimulating molecule such as cytokine' (see lines 30 and 31 on page 5 of the specification). A second heterologous peptide, polypeptide or protein such as cytokine does not provide descriptive support for a second peptide or protein from *L. intracellularis*. Furthermore, there is no support for a composition comprising an isolated immunogenic heatshock protein of *L. intracellularis* having the amino acid sequence of SEQ ID NO: 2 and 'a second heatshock protein'. Therefore, the above-identified limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitation(s), or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. 112, First Paragraph (Scope of Enablement)

27) Claims 32, 33, 37, 39, 40 and 114-116 are rejected under 35 U.S.C § 112, first paragraph, because the specification, while being enabling for a composition for administration to an animal comprising a pharmaceutically acceptable carrier and an isolated heatshock protein of *L. intracellularis* having the amino acid sequence comprising SEQ ID NO: 2 in an amount effective to induce an immune response in said animal, and a method for inducing an immune response in said animal comprising administering the composition to said animal, does not reasonably provide enablement for: (a) A composition comprising an isolated heatshock protein of *L. intracellularis* having the amino acid sequence comprising SEQ ID NO: 2 as recited and 'a second protein', for example, selected from the group consisting of flagellar basal body rod protein (SEQ ID NO: 7 for example); enoyl acyl-carrier protein reductase (SEQ ID N: 16, SEQ ID NO: 19 and SEQ ID NO: 20 for example); and glucarate transporter protein (SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 26 and SEQ ID NO: 27 for example); (b) A method for treating an animal infected by *L. intracellularis* comprising administering to said animal a composition comprising a

pharmaceutically acceptable carrier and an isolated heatshock protein of *L. intracellularis* having the amino acid sequence of SEQ ID NO: 2 alone, or in combination with 'a second protein' selected from the group consisting of a refolding protein; a second heatshock protein; flagellar basal body rod protein (SEQ ID NO: 7 and 8); an S-adenosylmethionine, tRNA ribosyltransferase-isomerase (SEQ ID NO: 13 and 14); enoyl acyl-carrier protein reductase (SEQ ID N: 16-20); and glucarate transporter protein (SEQ ID NO: 22-27), as recited currently. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

The instant claims are evaluated based on the *Wands* analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- The quantity of experimentation necessary (time and expense);
- The amount of direction or guidance presented;
- The presence or absence of working examples of the invention;
- The nature of the invention;
- The state of the art;
- The relative skill of those in the art;
- The predictability or unpredictability of the art; and
- The breadth of the claims.

In the instant case, the specification lacks evidence showing that a composition comprising a pharmaceutically acceptable carrier and an isolated heatshock protein of *L. intracellularis* having the amino acid sequence of SEQ ID NO: 2 alone, or in combination with 'a second protein' selected from the group consisting of a refolding protein; a second heatshock protein; a flagellar basal body rod protein; enoyl acyl-carrier protein reductase; and glucarate transporter, can treat an animal infected by *L. intracellularis*. To be enabled, a method of treatment is required to use animals already infected by *L. intracellularis* and administer to the infected animals the claimed composition comprising the isolated polypeptide of SEQ ID NO: 2 alone or in combination with the recited protein(s) or polypeptide(s). In the instant case, no animals already infected by *L. intracellularis* have been administered with such a composition. There is no showing within the instant specification that the polypeptide in the claimed composition, alone or in combination, induced therapeutic effects in an animal already infected with *L. intracellularis*.

Furthermore, the composition claimed, for example in claims 40 and 114-116, is required to contain a 'second protein' from *L. intracellularis*, or at least one other 'polypeptide selected from the group consisting of: flagellar basal body rod protein (SEQ ID NO: 7 for example); enoyl acyl-carrier protein reductase (SEQ ID N: 16, SEQ ID NO: 19 and SEQ ID NO: 20 for example); and glucarate transporter protein (SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 26 and SEQ ID NO: 27 for example). Example 20 of the instant specification describes that the amino acid sequences of SEQ ID NO: 7 and 8, encoded by the nucleotide sequence SEQ ID NO: 6, have sequence similarity to flagellin basal body rod protein of unknown structure and origin. The amino acid sequences of SEQ ID NO: 10 and 11, encoded by the nucleotide sequence of SEQ ID NO: 9, are described as having sequence similarity to an autolysin of unknown structure and origin. Similarly, the amino acid sequences of SEQ ID NO: 13 and 14, encoded by the nucleotide sequence of SEQ ID NO: 12, are described as showing sequence similarity to S-adenosylmethionine t RNA ribosyltransferase-isomerase (queuosine biosynthesid protein queA) of unknown structure and origin. The amino acid sequences of SEQ ID NO: 16-20, encoded by the nucleotide sequence of SEQ ID NO: 15, are described as showing sequence similarity to enoyl-(acyl-carrier protein) reductase of unknown structure and origin. The amino acid sequences of SEQ ID NO: 22-27, encoded by the nucleotide sequence of SEQ ID NO: 21, are described as showing sequence similarity to a glucarate transporter of unknown structure and origin. In the Table on page 19 and in the Sequence Listing filed in this application, the flagellar basal body rod protein is stated to be represented by SEQ ID NO: 7 and 8. However, SEQ ID NO: 7 is 12 amino acid-long. Similarly, enoyl-(acyl-carrier-protein) reductase protein is stated to be represented by SEQ ID NO: 16-20. However, SEQ ID NO: 16 for example is only 3 amino acid-long; SEQ ID NO: 20 is 9 amino acid-long; and SEQ ID NO: 19 is 11 amino acid-long. Furthermore, the glucarate transporter protein is stated to be represented by SEQ ID NO: 22-27. However, SEQ ID NO: 23 is as short as 2 amino acids-long; and SEQ ID NO: 26 and 25 are only 5 amino acids-long and 7 amino acids-long respectively. The description in Example 20 indicates that these 'proteins' or 'polypeptides' are not actually characterized with regard to their functions, for example, as an enoyl reductase enzyme, ribosyltransferase-isomerase enzyme, autolysin etc., but are merely referred as such based on

'sequence similarity'. However, the extent or degree of 'sequence similarity' with a known other protein of the recited enoyl reductase activity, ribosyltransferase-isomerase activity, or autolysin activity is not disclosed. What degree of sequence similarity does the recited second protein or polypeptide has with another protein or polypeptide of what structure and/or origin is not disclosed. Without the disclosure of the structure, origin and/or size of the various proteins or polypeptides to which the amino sequences of the recited proteins or polypeptides are to be compared in order to determine the 'sequence similarity', one of skill in the art cannot practice the full scope of the instant invention as claimed. There appears to be no evidence that these 'proteins' or 'polypeptides' comprising SEQ ID NO: 4, 7, 8, 10, 11, 13, 14, 16-20 and 22-27 were indeed tested for the enzymatic activity, autolysin activity, or any other activity. Absent a disclosure of the structure and/or origin of the reference protein or polypeptide, i.e., the flagellar basal body rod protein, the refolding protein, the second heatshock protein, the S-adenosylmethionine, the tRNA transferase-isomerase, the autolysin, the enoyl-(acyl-carrier-protein) reductase, and the glucarate transporter protein; and the precise degree of sequence similarity with the claimed polypeptides or proteins; the functional property, i.e., enoyl reductase activity, tRNA transferase-isomerase, or autolysin activity etc. of a protein or polypeptide is not predictable. If the sequence similarity was 10%, for example, it is unlikely that such a polypeptide or protein would retain the autolytic, tRNA transferase-isomerase, or enoyl-(acyl-carrier-protein) reductase functions. A two amino acid-long sequence, three amino acid-long sequence, or seven amino acid-long amino acid sequence, even if it shows 100% sequence similarity to an enoyl-redutase, tRNA ribosyltransferase-isomerase, or autolysin of known or unknown origin or a portion thereof, is unlikely to serve as a functional reductase, isomerase, or autolysin. Furthermore, the nucleotide sequences of SEQ ID NO: 5 and SEQ ID NO: 28-34 are stated to encode 'putative vaccine candidates'. However, there is absolutely no showing that these sequences did contain an ORF or did encode 'putative vaccine candidates', and that they were combinable in a composition for treating an animal, or for inducing an immune response against *L. intracellularis* in an animal. How to determine that the proteins or polypeptides encoded by these nucleotide sequences are 'putative vaccine candidates' is not taught. The structural composition of proteins allegedly encoded by SEQ ID NO: 5 and SEQ ID NO: 28-34 is not

disclosed, and their use in a composition for administration to an animal for prophylactic and therapeutic purposes is not enabled. Therefore, due to the lack of specific disclosure and guidance, the breadth of the claims, the unpredictability factor associated with the polypeptide structure-function relationship, and the quantity of experimentation necessary, undue experimentation would have been required by those of skill in the art to practice the invention as claimed. Instant claims are viewed as not meeting the enablement provisions of 35 U.S.C § 112, first paragraph.

Rejection(s) under 35 U.S.C. 112, Second Paragraph

28) Claims 1, 2, 12, 32, 33, 37, 39, 40 and 114-116 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is vague in the recitation 'heatshock protein ..... having an amino acid sequence comprising SEQ ID NO: 2'. In order to distinctly claim the subject matter and/or for clarity, it is suggested that Applicants replace the recitation with --heatshock protein ..... comprising the amino acid sequence of SEQ ID NO: 2--.

(b) Claim 1 is confusing and incorrect in the recitations: '*L. intracellulari*' (see line 3) and '*L. intracellularia*' (see line 5), which are inconsistent with the limitation '*L. intracellularis*' of claims 32, 37 and 116.

(c) Claim 1 is vague and indefinite in the limitation: 'induce an immune response against *L. intracellularis*', because it is unclear in whom the immune response is being induced.

(d) Claim 12 is vague in the recitation 'a nucleic acid having a sequence comprising SEQ ID NO: 1'. In order to distinctly claim the subject matter and/or for clarity, it is suggested that Applicants replace the recitation with --a nucleic acid having the nucleotide sequence of SEQ ID NO: 1--.

(e) The term "effective" in claim 32 is a relative term which renders the claim indefinite. The term "effective" is not specifically defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the claim.

(f) Claims 40 and 116 are vague, indefinite and/or confusing in the recitation: 'protein

... selected from the group consisting of ... flagellar basal body protein, ... enoyl-(acyl-carrier-protein) reductase, ... glucarate transporter'. For example, in the Table on page 19 and in the Sequence Listing filed in the application, the flagellar basal body protein is stated to be represented by SEQ ID NO: 7 and 8. SEQ ID NO: 7 is 12 amino acid-long. Similarly, enoyl-(acyl-carrier-protein) reductase is stated to be represented by SEQ ID NO: 16-20. SEQ ID NO: 16 for example is only 3 amino acid-long; SEQ ID NO: 20 is 9 amino acid-long; and SEQ ID NO: 19 is 11 amino acid-long. Furthermore, the glucarate transporter protein is stated to be represented by SEQ ID NO: 22-27. SEQ ID NO: 23 is as short as 2 amino acids-long; SEQ ID NO: 26 and 25 are only 5 amino acids-long and 7 amino acids-long respectively. It is unclear how a 2 or 3 amino acid-long amino acid sequences can represent a 'protein'. It is further unclear how a 3 amino acid-long amino acid sequence can represent a 'reductase' enzyme, or have a reductase enzyme activity.

(g) Analogous criticism applies to claim 115.

(h) Claim 114 is further vague, indefinite and confusing in the recitation: 'polypeptide selected from the group consisting of SEQ ID NO: .... 16-20, and 22-27'. From the substitute Sequence Listing submitted 08/03/00, it appears that SEQ ID NO: 23 is just 2 amino acids long, and SEQ ID NO: 16 is three amino acids long. It is unclear how these sequences can be regarded as 'polypeptides'. The same is true with other SEQ ID numbers, such as, SEQ ID NO: 25 and 26, which are 7 and 5 amino acids in length respectively.

(i) Claim 114 is indefinite and/or confusing in the recitation: 'polypeptide selected from the group consisting of: SEQ ID NOS: .....'. Since the recited SEQ ID numbers represent amino acid sequences, it is suggested that Applicants replace the recitation with --polypeptide comprising the amino acid sequence selected from the group consisting of SEQ ID NO: .....--.

(j) Claim 115 is vague, indefinite and confusing in the recitation: 'one other protein ..... encoded by the nucleotide sequence selected from the group consisting of SEQ ID NOS: .....12, 15, ..'. From the substitute Sequence Listing submitted 08/03/00 and the Table on page 19 of the specification, it does not appear that SEQ ID NO: 12, 15 and 21 encode a single 'protein'.

(k) Claims 40 and 116 are vague and indefinite in the limitations: 'an S-adenosylmethionine, tRNA ribosyltransferase-isomerase'. It is unclear whether these represent two

different proteins of *L. intracellularis*, or a single protein of *L. intracellularis*?

(l) Claims 2, 12, 32, 33, 37, 39, 40 and 114-116, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness or vagueness identified above in the base claim.

Objection(s)

29) Claims 37 and 40 are objected to for the following reasons:

(a) In line 2 of claim 37, the comma after the recitation 'protein' is improper and/or unnecessary.

(b) In line 1 of claim 40, for clarity, it is suggested that Applicants replace the recitation 'the-second' with --the second--.

Remarks

30) Claims 1, 2, 12, 32, 37, 39, 40 and 114-116 stand rejected.

31) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306.

32) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

33) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September, 2004

S. DEVI, PH.D.
PRIMARY EXAMINER